

REMARKS

Amendments to the Claims

For clarity and to submit claims that correspond with the elected invention, claims 1-23 are cancelled and re-written as new claims 24-40; however, Applicants reserve the right to prosecute the original scope of the elected and cancelled claims in a later related application. Applicants submit that no new matter is added with new claims 24-40, as these new claims are merely re-written and re-numbered claims which correspond to various previously submitted claims 1-23.

Claim Rejections Under 35 U.S.C. § 102(b)- Anticipation

Claims 2-23 are rejected as being anticipated by PCT application WO 95/07274 to Kerrigan et al (herein "Kerrigan"). The Action Kerrigan "teaches the synthesis of benzodioxan derivatives for the treatment of drug abuse, drug addiction and eating disorders"

Applicants respectfully submit that Kerrigan does not anticipate the presently claimed subject matter of the instant application, as herein amended. For a reference to anticipate an invention under 35 USC § 102 the reference must teach every element of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present and the Examiner must provide rationale or evidence tending to show inherency. See MPEP §706.02, §2112, and §2131. In addition, for anticipation, the "identical invention must be shown in as complete detail as is contained in the patent claim." (see *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed.Cir. 1989) (hereinafter "*Richardson*")) Further, the cited reference must contain an enabled disclosure (MPEP §2131.01).

First, the cited reference, Kerrigan, does not teach each and every element of the cited invention. The presently claimed invention is directed to "A method *of reducing cravings to food* which comprises the administration of a therapeutically effective amount of a compound of formula I ... or pharmaceutically acceptable salts thereof ... to a patient in need thereof." See claim 24, emphasis added. Nothing in Kerrigan teaches a method to reducing cravings to food, either explicitly or impliedly. Kerrigan teaches a

“method of treating depression, anxiety, psychoses, Parkinson’s disease, obesity, hypertension, Tourette’s syndrome, sexual dysfunction, drug addiction, drug abuse, cognitive disorders, Alzheimer’s disease, senile dementia, obsessive-compulsive behaviour, panic attacks, *eating disorders*, *anorexia*, cardiovascular and cerebrovascular disorders, non-insulin dependent diabetes mellitus, hyperglycaemia, constipation, arrhythmia, disorders of the neuroendocrine system, stress, prostatic hypertrophy or spasticity which comprises the administration of a therapeutically effective amount of a compound of formula I....”

Nowhere in that list of conditions is there a listing of “cravings for food,” whether explicitly or impliedly. Moreover, a claim to a “method of *treating*” a lengthy series of conditions/disorders/diseases is not the same as a “method of *reducing cravings*.” In fact, the only two conditions which remotely deal with food – eating disorders and anorexia – do not follow from a method to reduce cravings to food. It makes no sense that a method to treat anorexia would impliedly be the same as a method of reducing cravings to food; such a treatment would in fact only make the patient worse. The whole point in treating someone with anorexia is to get them to eat, not reduce their cravings to food.

Similarly, a method of treating eating disorders does not impliedly teach a method for reducing cravings to food. Kerrigan does not define what constitutes eating disorders or what it means to treat them. One can envision that anorexia and bulimia might fall within the category of an eating disorder, but does the category also encompass gastric reflux disease? Inflammatory bowel disease? Lactose intolerance? Binge eating? Fad diets that encompass bizarre and unhealthy dietary requirements, such as eating only grapefruits, eating only meat, eating only carbohydrates, eating only ice cream? Applicants respectfully submit that it is not possible to conclude that a method of treating eating disorders explicitly or impliedly teaches a method of reducing cravings to food when one cannot determine from the disclosure of Kerrigan either what constitutes an eating disorder, or more importantly, what it means to treat an eating disorder.

Second, the feature not directly taught by Kerrigan (reducing cravings to food) is also not inherently present in Kerrigan. As held in *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed.Cir. 1991) “To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference

may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by person of ordinary skill.” Moreover, the Examiner must provide rational or evidence tending to show inherency (see MPEP §2112). As held in *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed.Cir. 1993) “[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” In the present case, there is no extrinsic evidence that has been presented to fill in the “gap” and show how one of ordinary skill would get from “treating eating disorders” to “reducing cravings to food” given that there is absolutely no experimental evidence disclosed in Kerrigan for treating an eating disorder, no discussion of what an eating disorder is (is it physiological or psychological?) and no discussion, even in the vaguest of terms, for how one *might* treat an eating disorder.

Third, even if one were to find that Kerrigan teaches a method of reducing cravings to food, whether explicitly or impliedly, Kerrigan does not teach the invention “in as complete detail as is contained in the patent claim” as required by *Richardson* (see above). All of the examples in Kerrigan relate to either how to synthesize and purify compounds of formula I (see Examples 1-28) or how to prepare pharmaceutical compositions (Example 29). And to establish therapeutic activity, rat brains were homogenized and *in vitro* tests were performed with various concentrations of compounds of Formula I for their ability to displace a specific ligand for 5-hydroxytryptamine (5-HT) receptors. From this data K_i values for the binding of various compounds to 5-HT receptors were determined. There is nothing in Kerrigan that explains the relationship between 5-HT receptors and treating eating disorders, and no discussion of how this data collected in rats relates to the treatment of any condition, let alone a human eating disorder.

And finally, Kerrigan is not enabled for a method of reducing cravings to food. As discussed above, the only data showing biological activity for the compounds of Formula I was done *in vitro*, with rat brain tissue, to determine K_i values for binding to 5-HT receptors. There is no *in vivo* data, no data in humans, no discussion of how the 5-HT receptors are involved in eating disorders, no discussion of what constitutes an eating

disorder or what it means to treat one, and not so much as a hypothetical example for how one might actually treat an eating disorder in humans.

For at least the reasons stated above, Applicants respectfully submit that none of the pending claims are anticipated by WO 95/07274 to Kerrigan et al. Withdrawal of the anticipation rejection under 35 USC §102(b) is therefore requested.

Claim Rejections Under 35 U.S.C. § 112, para. 2- Indefiniteness

Claims 2-23 stand rejected as being unpatentable for reasons of indefiniteness for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Actions recites objections to phrases “including” or “includes” in various claims, and “manufacturing a medicament” and “method of producing a substance” in claim 23.

Claims 1-23 are herein cancelled, and newly re-written and re-numbered claims 24-40 do not include any of the indefinite phrases or terms listed above. In particular, independent claims 24 and 33 state that the method comprises administration of a therapeutically effective amount of a compound of formula I ... “*or pharmaceutically acceptable salts thereof*” which replaces the previous language of claims 21 and others that recited “*including pharmaceutically acceptable salts thereof*” or other versions of the word “includes.” There is no new claim that is equivalent to claim previous 23.

For these reasons, Applicants respectfully submit that all claims are definite. Withdrawal of the indefiniteness rejections under 35 USC § 112, para. 2 is therefore requested.

CONCLUSION

Claims 1 – 23 are cancelled without prejudice, but Applicant reserves the right to pursue such claims in a later related application, and new claims 24-40 are added. No new matter is added with these new claims, as they are simply re-written, and re-numbered, versions of claims already presented in previous claims 1-23.

In view of the arguments and amendments presented, Applicant respectfully submits that all pending claims are now in condition for allowance. Reconsideration of the claims and a notice of allowance are therefore respectfully requested.

Applicants believe that a two-month extension of time is required and submit a petition for a two-month extension with this response along with a check for \$1190 to cover the two-month Extension Fee (\$420) and the fee for a Request for Continued Examination (\$770) for a large entity. In the event that an additional extension is required, however, this conditional petition for a further additional extension of time is requested and Applicants also request that any additional fees required for the timely consideration of this application be charged to deposit account number 19-4972.

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Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Barb J. Carter".

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